ESKA-LIBUR Hip Stem
510(k) Summary

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Date December 19, 2005

Submitter ESKA Implants GmbH & Co.

JAN 20 2006

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name ESKA-LIBUR Hip Stem

Common name Press-fit hip

Classification name Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
Class II per 21 CFR section 888.3358

Product Code LPH

Equivalent Device The ESKA-LIBUR Hip Stem is a modification to the ESKA Modular Hip System (K993027). It has the same indications, similar geometry, the same material and the same Spongiosa Metal II® Surface.
The ESKA-LIBUR hip is also similar in modular neck design as the R120 Total Hip (Osteoimplant Technology, Inc. K0117774/K021822) and the Profemur Hip (Wright Technology K041586).

Device Description
The ESKA-LIBUR Hip Stem is fabricated from cast CoCrMo alloy that conforms to ASTM F75 and ISO 5843-4. The stem is available in thirteen sizes with a distal M/L dimension ranging from 9mm to 13.5mm, and lengths from 120mm to 180mm. It is modular in nature such that a female Morse type taper on the proximal body accepts an adaptor that has male tapers on both ends. One end engages the hip stem and the other a modular head.

The distal end of the stem is color buffed while proximal body has the same Spongiosa Metal II® Surface cast into same as the predicate ESKA Modular Hip Stem.

Intended Use
The ESKA-LIBUR Hip Stem is indicated for use in the treatment rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, vascular necrosis, non-union of femoral neck fractures, fracture dislocation of the hip, conversion of unsuccessful arthodeses and revision of previous hip surgeries.

Summary Nonclinical Tests
The ESKA-LIBUR Hip Stem was tested according to ISO 7206-4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2006

ESKA Implants GmbH & Co
c/o Mr. J. D. Webb
Orthomedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K053557
Trade/Device Name: ESKA LIBUR Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: December 19, 2005
Received: December 21, 2005

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053557

Device Name: ESKA-LIBUR Hip Stem

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053557